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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,822	08/21/2002	Vincent E. Manetta	P22,901-A USA	9998

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,822	MANETTA ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38 and 46-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38 and 46-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for Continued Examination and Amendments/Remarks filed 6/29/06 is acknowledged. Claims **38 and 46-58** are pending in this application. Claims 1-37 and 39-45 stand cancelled.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. However, the examiner has retained WO 99/02133 to Lefevre et al and WO 97/27841 to Edens et al; thus applicant's arguments pertaining to Lefevre and Edens will be discussed.

Applicant argues that WO '133 does not teach a gel formulation and the instant claims have been amended to recite a gel composition. This argument is not persuasive since it is the examiner's position that WO clearly teaches a gel formulation. Firstly, it is pointed out that Lefevre uses gelling agents such as Carbopol in the benzoyl peroxide and erythromycin compositions respectively. See page 8. Moreover, Lefevre specifically teaches on page 4 the use of the viscosity modifying agents "for **gellifying** an aqueous suspension...". Further, although WO utilizes the terminology "suspension" this does not mean the composition is not in a gel form. The term "suspension" merely describes the state of the benzoyl peroxide in the composition; in other words the benzoyl peroxide is in an undissolved state in the carrier. Applicant has incorrectly assumed that a suspension cannot be a gel. The examiner points out that WO '133 itself states that the aqueous suspension is gellif[ied].

Applicant argues that although example 1 of WO '133 uses Carbopol as the viscosifier, Lefevre uses the term "solution". Thus, applicant argues a solution is clearly not a gel. This

argument is not persuasive for the following reasons: firstly the examiner points out that when a gel is heated it exists in a solution form. This is evidenced by the definition supplied by applicant. A gel is *a colloidal solution* usually formed by cooling into a solid or semisolid phase. The examiner points out that example 1 heats the "clear solution" to combine the erythromycin, ethanol, and Carbopol. Note the clarity of a composition does not effect the viscosity of a composition. Thus, the term "clear" does not preclude a gel form as argued by applicant. Secondly, the examiner points out that once a gelling agent is added to a composition, it inherently increases the viscosity of the composition depending on its concentration. This is known in the art and substantiated by not only by Lefevre's disclosure (Lefevre specifically teaches on page 4 the use of the viscosity modifying agents for gellifying an aqueous suspensions) but also by Smith et al. Smith discloses, "The present peroxide-containing vehicles will comprise an amount of an inorganic or organic gelling agent effective to gel or thicken the aqueous-alcoholic mixture to at least a cream- or lotion-like consistency". Lastly, the examiner points out that the prior art does not need to explicitly use the term "gel" to read on the instant invention. The examiner points out that the use of Carbopol (a carbomer) is implicit that the composition is in gel form since Carbopol is a gelling agent as evidenced by the WO '133; US 5,562,642; and US 6,211,250. Therefore, it is the examiner's position that Lefevre clearly teaches a gel composition and the only teaching lacking is 1) Lefevre does not specify the viscosity and 2) Lefevre does not teach the instant gelling agent HPC.

Applicant argues that Lefevre only teaches a composition with a viscosity of 100 to 30,000 cps and not the instantly claimed viscosity. The examiner acknowledges WO '133 teaches a preferable range of 100 to 30,000 cps; thus the rejection is made under obviousness. It

should be noted that, "disclosed examples and preferred embodiments do not constitute a teaching away form the broader disclosure or nonpreferred embodiment". In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Lefevre also *generally* teaches using a viscosifying agent to provide the desired viscosity and teaches the importance of formulating the individual composition with the same viscosity to ensure that both the compositions are dispensed simultaneously from the dispenser. Thus, a skilled would have expected similar results by increasing the viscosity of the composition as long as the critical aspect was maintained, i.e. ensuring that both are formulated with the same viscosity.

Applicant argues that WO 97/27841 to Edens et al (refers to the pouch utilized in US 4,823,985) does not teach the instant dispenser since it is not capable of being folded. This argument is not found to be persuasive since the examiner points out that US '985 discloses, a "dispensing assembly incorporating two containers respective ones of which contain the two components A and B intended to form one and the same composition by simultaneous dispensing, wherein the containers have, on the other hand, a deformable wall enabling them to be compressed simultaneously by successive squeezing actions by the user in order to provide for the dispensing of their contents, and on the other hand outflow orifices which are close together or capable of being brought into proximity with each other, and arranged in such a way that their outflow jets meet each other, the said outflow orifices being capable of being opened simultaneously". Thus, the pouch is capable of being folded along it common side since it made to flexible material. Further, the examiner notes that the specification discloses the criticality of the claimed pouch is its ability to maintain the compositions in a separate container and yet

simultaneously dispense the individual compositions and the pouch disclosed in WO '841 and taught as suitable by WO '133 clearly provides the means to do this.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

Claim 51 and 52 recite "0.3 to 0.5% sodium hydroxide" which not have support in the specification and claims as originally filed. Applicant contends that claim 51-52 has support since claim 44-45 claimed the same limitation; this is not sufficient support since claims 44-45 are not originally filed claims. However, upon a careful review of the specification, page 31 only provides support for 0.1-1%, preferably 0.15-0.4%, and 0.2-0.35%.
However, if applicant contends there is support for the above limitations, the applicant is requested to cite the page and specific line where said support is found.

The rejection of claims 38-39 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicant's amendments of 6/29/06 and applicant's argument.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 23-35 under 35 U.S.C. 103(a) as being unpatentable GB 2088717 to Klein et al in view of Smith et al (5,562,642) are withdrawn in view of the cancellation of claims 1-37.

The rejection of claims 18-21, 23-24, 26-30, 32-37, 39-42, and 44-45 under 35 U.S.C. 103(a) as being unpatentable over WO 99/02133 to Lefevre et al in view of Smith et al (5,562,642) optionally in further view of Fowler et al (5,534,265) are withdrawn in view of the cancellation of claims 1-37.

Claims 38, 47, 49, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/02133 to Lefevre et al in view of in view of WO 97/27841 to Edens et al in further view of Deckner et al (5,707,635).

Lefevre teaches a topical application of a combination of benzoyl peroxide and a second active ingredient in a multi-compartment dispensing system. The dispensing system contains a first composition of benzoyl peroxide and a second active ingredient selected from an antifungal agent or an antimicrobial agent. See abstract. The first and second compositions generate a final composition that is mixed upon delivery. See page 2, lines 20-30. The preferred second active agent is erythromycin, natamycin, clindamycin, or linocomycin. See page 3, lines 19-25. The ratio of the two active agents may be adjusted between the range of 1:1 to 1:50 and preferably 1:2 to 1:20. See page 4, lines 34-38. The concentration of the benzoyl peroxide is between 2-15% and the amount of erythromycin is up to 30%. See page 5. The final concentration of benzoyl peroxide in the mixed composition is 5% and 3% erythromycin.

The reference teaches the use of a viscosity agent to yield the desired viscosity. Viscosity agents for gelling are **Carbopol** 940 and **hydroxypropylmethylcellulose**. Additional viscosity agents are Carbopol Ultrez, xanthan, and carrageenans. The amount of the viscosity agent of **0.1-3%.** The solvents disclosed are ethanol, polyethylene glycol, propylene glycol, and glycerol. See page 4. Sodium hydroxide is taught to render the desired pH.

In a preferred embodiment, the first composition contains **5% benzoyl peroxide** suspended in an aqueous suspension adjusted with sodium hydroxide to a pH of 8 and **Carbopol** 940 (viscosifying agent- reads on claim 42). The second composition contains 30% **erythromycin** dissolved in 96% ethanol and **Carbopol** Ultrez. The viscosity of the erythromycin composition is comparable to the viscosity of the benzoyl peroxide gel. The final composition yields an end concentration of 3% erythromycin and 5% benzoyl peroxide. See page 6, lines 9-30 and example 1.

Lefevre states that a dispensing system that allows for separate containment as well as simultaneous dosing is preferred. The system has two chambers adjacent to each other that ensures separation and simultaneous dosing and each chamber has an orifice in which the composition is dispensed from. Further, the system has a dosing pump. The disclosure of WO 97/27841 in regards to the dispensing system is incorporated in to Lefevre. See page, lines 10-18.

Although Lefevre teaches the dispensers taught in WO 97/27841 are suitable, Lefevre does not specify the use of two pouches in a parallel relationship that share a common side that is capable of being folded along the common side. Secondly, Lefevre does not teach the instantly claimed viscosity.

Eden teaches several dispensing systems to simultaneously dispense active agents that need to be stored separately until use wherein they are mixed together for application to the skin. Eden teaches a "simple" dispensing system wherein a pair of plastic pouches are in a parallel relationship wherein the outlets for the pouches are close together and discharge the contents upon the tearing of the opening at the end of the pouch as disclosed in DE 3630849. See page 9, lines 27-32. The bag of DE specifically is made of flexible material wherein the two pouches are side by side, sharing a common side. Example 12 teaches a dispenser with two separate pouches that dispense two separate compounds in equal volumes.

Deckner et al teach a gel type cosmetic composition which provides improved skin feel, residue characteristics, and rub-in and absorption characteristics. See abstract. Deckner teaches various suitable pharmaceuticals and preferably anti-acne drugs including benzoyl peroxide and erythromycin. See column 4, lines 5-16. The composition has a viscosity of at least 4,000, preferably 4,000-300,000, and preferably 20,000-200,000cps. See column 6, lines 44-60.

Deckner teaches the use of polyacrylamide gelling agents and additional hydrophilic gels including cellulose ethers.

Firstly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of WO '133 and WO '841 and utilize a dispenser that has two pouches in a parallel relationship with a foldable common side. WO 97/27841 teaches several types of systems including the instantly claimed dispensing system and Lefevre states that any type of dispenser disclosed in WO 97/27841 is suitable to hold the benzoyl peroxide gel and erythromycin gel respectively. Therefore, it would have been obvious to utilize any dispensing system disclosed in Edens to separate the benzoyl peroxide gel and erythromycin gel since the critical feature of the dispensing system is that it ensures separation of the compositions held in the respective pouches. Thus, one would have been motivated to utilize the system wherein two pouches are in a parallel relationship since Edens teaches this is a simple dispensing system. Note that the simple pouch system described in Eden is capable of being folded along it common side since it made to flexible material and thus reads on the instant limitation "foldable" (able to fold).

Secondly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further look to the teachings of Deckner et al and manipulate the viscosity of Lefevre's gel compositions. One would have been motivated to do so since Deckner teaches anti-acne gels that may have a viscosity ranging from 4,000-300,000 and 20,000-200,000 cps to increase residue, rub-in, and absorption properties. Therefore a skilled artisan would have been motivated to increase the viscosity of Lefevre's gel composition since Deckner establishes the state of the art where it is known to formulate gels particularly anti-acne (benzoyl peroxide and

erythromycin) gels with viscosities ranging from 4,000-300,000 cps. Moreover, although Lefevre teaches a preferred viscosity of 100-30,000 cps, this is only a preferred range. Thus, a skilled artisan would have expected similar results since Lefevre teaches the critical aspect of the viscosity is that both compositions (the peroxide and antibiotic compositions respectively) have similar viscosities. Therefore, a skilled artisan would have been motivated to increase the viscosity of both compositions to increase its residue, rub-in, and absorption properties.

With regard to claim 52, firstly note that the claim is rejected under new matter. Secondly, the manipulation of the concentration of sodium hydroxide is dependent on the desired pH.

Claims 38, 46-49, 52-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/02133 to Lefevre et al in view of in view of WO 97/27841 to Edens et al in further view of Smith et al (5,562,642), optionally in further view of Tomlinson et al (6,211,250).

Lefevre teaches a topical application of a combination of benzoyl peroxide and a second active ingredient in a multi-compartment dispensing system. The dispensing system contains a first composition of benzoyl peroxide and a second active ingredient selected from an antifungal agent or an antimicrobial agent. See abstract. The first and second compositions generate a final composition that is mixed upon delivery. See page 2, lines 20-30. The preferred second active agent is erythromycin, natamycin, clindamycin, or linocomycin. See page 3, lines 19-25. The ratio of the two active agents may be adjusted between the range of 1:1 to 1:50 and preferably 1:2 to 1:20. See page 4, lines 34-38. The concentration of the benzoyl peroxide is between 2-

15% and the amount of erythromycin is up to 30%. See page 5. The final concentration of benzoyl peroxide in the mixed composition is 5% and 3% erythromycin.

The reference teaches the use of a viscosity agent to yield the desired viscosity. Viscosity agents for gelling are **Carbopol** 940 and **hydroxypropylmethylcellulose**. Additional viscosity agents are Carbopol Ultrez, xanthan, and carrageenans. The amount of the viscosity agent of **0.1-3%.** The solvents disclosed are ethanol, polyethylene glycol, propylene glycol, and glycerol. See page 4. Sodium hydroxide is taught to render the desired pH.

In a preferred embodiment, the first composition contains **5% benzoyl peroxide** suspended in an aqueous suspension adjusted with sodium hydroxide to a pH of 8 and **Carbopol** 940 (viscosifying agent- reads on claim 42). The second composition contains 30% **erythromycin** dissolved in 96% ethanol and **Carbopol** Ultrez. The viscosity of the erythromycin composition is comparable to the viscosity of the benzoyl peroxide gel. The final composition yields an end concentration of 3% erythromycin and 5% benzoyl peroxide. See page 6, lines 9-30 and example 1.

Lefevre states that a dispensing system that allows for separate containment as well as simultaneous dosing is preferred. The system has two chambers adjacent to each other that ensures separation and simultaneous dosing and each chamber has an orifice in which the composition is dispensed from. Further, the system has a dosing pump. The disclosure of WO 97/27841 in regards to the dispensing system is incorporated in to Lefevre. See page, lines 10-18.

Although Lefevre teaches the dispensers taught in WO 97/27841 are suitable, Lefevre does not specify the use of two pouches in a parallel relationship that share a common side that is

capable of being folded along the common side. Secondly, Lefevre does not teach the instantly claimed viscosity or the instant gelling agent (HPC).

Eden teaches several dispensing systems to simultaneously dispense active agents that need to be stored separately until use wherein they are mixed together for application to the skin. Eden teaches a "simple" dispensing system wherein a pair of plastic pouches are in a parallel relationship wherein the outlets for the pouches are close together and discharge the contents upon the tearing of the opening at the end of the pouch as disclosed in DE 3630849. See page 9, lines 27-32. The bag of DE specifically is made of flexible material wherein the two pouches are side by side, sharing a common side. Example 12 teaches a dispenser with two separate pouches that dispense two separate compounds in equal volumes.

Smith et al teaches a system for applying a plurality of incompatible dermatological agents to the skin. See abstract. The composition may be in various forms such as powders, gels, dispersions, and solutions. See column 4, lines 1-2. Smith teaches the use of gelling agents, which thicken and gel aqueous-alcoholic mixtures to at least a cream or lotion consistency. Smith teaches the use of organic gelling agent such as microcrystalline cellulose, hydroxyalkyl cellulose ethers such as hydroxypropylmethylcellulose, hydroxypropylcelluose (HPC), hydroxymethylcellulose, and Carbopols etc. See column 14, lines 5-35. The gelling agent is used in the amount of 0.1% to about 15% and preferably about 0.5-3%. See column 15, lines 1-3. Furthermore, Smith teaches the use of HPC and the gelling agent of choice in combination with benzoyl peroxide, which yields a thicker fluid gel. See column 17, lines 40-68. Smith teaches the use of surfactants to stabilize the gel formulation.

Tomlinson teaches a percutaneous delivery system for antimicrobial, antifungal, and antiviral agents. See abstract. Tomlinson teaches the gel composition has good substantivity to the skin. See column 2, lines 50-55. The gel comprises a hydrophilic polymer selected from hydroxypropylcellulose (HPC), hydroxypropylmethylcellulose, carbomers (carbopol is the trade name), or PVP in an amount of 0.5-30 and preferably 0.05-10%. See column 5, lines 55-65 and column 6, lines 10-15. Erythromycin is taught as a suitable active. See column 7, line 35. Tomlinson teaches the gel can range from different viscosities of 100cps to 200,000 due to the weight percent of HPC used. See column 13, lines 55-60.

Firstly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of WO '133 and WO '841 utilize a dispenser that has two pouches in a parallel relationship with a foldable common side. WO 97/27841 teaches several types of systems including the instantly claimed dispensing system and Lefevre states that any type of dispenser disclosed in WO 97/27841 is suitable to hold the benzoyl peroxide gel and erythromycin gel respectively. Therefore, it would have been obvious to utilize any dispensing system disclosed in Edens to separate the benzoyl peroxide gel and erythromycin gel since the critical feature of the dispensing system is that it ensures separation of the compositions held in the respective pouches. Thus, one would have been motivated to utilize the system wherein two pouches are in a parallel relationship since Edens teaches this is a simple dispensing system. Note that the simple pouch system described in Eden is capable of being folded along it common side since it made to flexible material and thus reads on the instant limitation "foldable" (able to fold).

Secondly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teachings of Smith et al and Tomlinson et al and manipulate the viscosity of Lefevre's gel compositions. It is the examiner's position that the manipulation of viscosity of a composition is known to those skilled in the art and it is prima facie obvious absent a showing of the unexpectedness of the instant viscosity. Tomlinson teaches the HPC is capable of providing a range of viscosities (100cps to 200,000 cps) depending on the concentration used. Thus, one would have been motivated to manipulate the viscosity of the composition by increasing or decreasing the concentration of the gelling agent, depending on the desired form. Therefore, a skilled artisan would have increased the concentration of the gelling agent if one desired a thickened gel, i.e. a semi-solid gel, rather than a fluidized gel.

Furthermore, Lefevre teaches the use of Carbopol (carbomer) or HPMC as the gelling agent in an amount of 0.1-3% and both Smith and Tomlinson teach the functional equivalency, (both act to thicken or "gel" a formulation) of the instantly claimed HPC and Lefevre's gelling agents (hydroxypropylmethylcellulose and carbomer). Therefore, it is prima facie obvious to substitute one equivalent component with another since the prior art establishes that both hydroxypropylcellulose and hydroxypropylmethylcellulose both function the same and are utilized for the same purpose, i.e. to thicken a skin formulation. Additionally, it is the examiner's position that the combination of Lefevre and Smith would necessarily provide the instantly claimed viscosity since WO '133 teaches 0.1-3% of the gelling agent and the use of 1-3% of HPC, which is encompassed by the claimed range of 1-4%. Note that Tomlinson substantiates this.

With regard to claim 52, firstly note that the claim is rejected under new matter. Secondly, the manipulation of the concentration of sodium hydroxide is dependent on the desired pH.

Claims 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/02133 to Lefevre et al in view of in view of WO 97/27841 to Edens et al in further view of Smith et al (5,562,642), in further view of Tomlinson et al (6,211,250) in further view of Klein et al (4,692,329).

As set forth above, Lefevre discloses a topical application of a combination of benzoyl peroxide and a second active ingredient in a multi-compartment dispensing system. As set forth above, Smith et al teach the functional equivalency of hydroxypropylcellulose and hydroxypropylmethylcellulose in a topical composition. As set forth above, Tomlinson teaches the instant viscosity and it manipulation with the weight percent of HPC.

The references do not teach the use of instant surfactant, dioctyl sodium sulfosuccinate.

Klein et al discloses an erythromycin and benzoyl peroxide composition, wherein the actives may be packaged separately. Klein et al teach the use of dioctyl sodium sulfosuccinate to provide stability to the peroxide component in the formulation. Further, the sulfosuccinate allows evaporation and uniform release of the peroxide compound so as to avoid burning and erythema. See column 3,lines 14-25. Klein also teaches the use of various gelling agents such as Example 13 discloses a gel formulation containing 5.46% benzoyl peroxide, 2% erythromycin, 44.10% ethanol, 6% polyoxyethylene lauryl ether, 2.50 colloidal magnesium aluminum (gelling agent), 1% hydroxymethylcellulose, 0.02% dioctyl sodium sulfosuccinate, and water. Sodium hydroxide and use of Carbopol as the gelling agent is taught in examples 11-12.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references above and further utilize the instant surfactant. One would have been motivated to do so since Klein teaches dioctyl sodium sulfosuccinate not only provides stability to a composition that contains both erythromycin and benzoyl peroxide but it also allows for the uniform release of the peroxide compound so as the avoid burning and erythema upon application. Therefore, one would be motivated to utilize the instant surfactant to increase stability and to avoid the side effects caused by the use of peroxides topically.

Conclusion

All the claims are rejected at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharmila S. Gollamudi
Examiner
Art Unit 1616